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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,011	08/05/2005	Andreas Boehm	P0777.70000US00	7235

23628 7590 10/13/2010

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EXAMINER	
DIXON, ANNETTE FREDRICKA	
ART UNIT	PAPER NUMBER
3771	
MAIL DATE	DELIVERY MODE
10/13/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/519,011	BOEHM ET AL.	
	Examiner	Art Unit	
	Annette F. Dixon	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 January 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is in response to the request for continued Examination filed on January 13, 2010. Examiner acknowledges claims 1-34 are pending in this application, with claims 1 having been currently amended.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 13, 2010 has been entered.

Claim Objections

3. Claims 1 and 8 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Specifically, claim 1 recites the flow resistance device is "configured to be placed at the other of the two alae of the user's nose"; while, claim 8 recites the flow resistance device is "configured for introduction into the other of the user's nostrils".

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 25-27 and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. No amendment may introduce new matter into the disclosure of an application after its filing date. MPEP §906.04.

Specifically, in Claim 25 the phrase "for example" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d). Dependent claims 26, 27, and 34 incorporate the indefinite subject matter from which they depend. Appropriate correction is required for ALL instances of the phrase "for example". Should Applicant wish to keep the listing of medicaments, Examiner suggests Applicant consider utilizing the language "selected from the group of: "typical of Markush claims

Specifically, in Claims 27 and 34, the phrase "approximately" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-3, 7-9, 11, 12, 16, 20, and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zimmerman (4,273,124) in view of Terada et al. (5,054,477).

As to Claims 1, 8, 29 and 30, Zimmerman discloses a nose piece (16) configured to supply aerosol (via 12) into one of the two alae of the nose and a flow resistance device (34) configured to be placed at the other of the two alae of the nose, the flow resistance device (34) causing aerosol (via 12) to reach the paranasal sinuses of the user and to be deposited therein. (Figure 8, and Column 5, Lines 18-20). Regarding the flow resistance limitation, the flow resistance device (34) has a narrowing cross section that limits the ability of air to be readily dispersed. Yet, Zimmerman does not disclose the source of aerosol is delivered by a nebulizer device in order to convey aerosol (via 12) to the patient. Terada teaches a nebulizer device (Figure 2, the combination of 10 and 20) having a aerosol generator (10) to which a gaseous medium (compressed air via 12, Column 3, Line 55) for the generation of a main aerosol flow may be supplied from a supply device (compressed air source, Column 3, Line 55) and a pressure connection device (46 to direct air though the air inlet flue 40) to supply pressure fluctuations which are superimposed on the aerosol main flow (via 12). Terada teaches the purpose of the nebulizer for providing efficient atomization of liquid to a patient. (Column 1, Lines 60-67). Therefore, it would have been obvious to modify the aerosol source of Zimmerman to include a nebulizer as taught by Terada to providing efficient atomization of liquid to a patient during respiratory therapy.

As to Claim 2, Terada teaches the supply device (compressed air source) is a compressed air supply device (12, Column 3, Line 55), and the aerosol generator (10) is a nebulizer nozzle (13) with a compressed air channel opening (3), with at least one suction channel (the combination of 1 and 2) though which a liquid (11) to be nebulized is drawn in.

As to Claim 3, Zimmerman discloses the nose piece (16) is configured for attachment (via 14) to a connecting piece (22) in the nebulizer device (Figure 2, the combination of 10 and 20) and at the other end is configured for introduction into one nostril and the tight sealing of one of the user's nostrils. (Column 3, Lines 33-36).

As to Claim 7, Zimmerman discloses an alternative nose piece (44) having an inflation balloon connection (via 46) for supplying a tight seal to the nostril of the patient. (Column 5, Lines 25-43).

As to Claim 9, Zimmerman discloses the flow resistance device (34) has an opening smaller than the user's nostrils in order for the flow resistance device (34) to be placed within the nostril. (Figure 8, and Column 5, Lines 18-20).

As to Claims 11 and 12, Zimmerman discloses a connection piece (the portion between the flow resistance device 34 and the nose piece 16, Figures 7 and 8) to connect the nose piece (16) and the flow resistance device (34).

As to Claim 16, Terada teaches the nebulizer device (the combination of 10 and 20) has an air inlet flue (40) and a pressure connection device (46) to supply pressure fluctuations (Column 9, Lines 21-35).

As to Claim 20, Terada teaches a rod (34) for modulating the pressure fluctuations (Column 9, Lines 21-35).

As to Claim 28 Terada teaches the nebulizer is easy to manufacture and handle without trouble (Column 6, Lines 35-38).

8. Claims 4-6 and 31are rejected under 35 U.S.C. 103(a) as being unpatentable over Zimmerman (4,273,124) in view of Terada et al. (5,054,477), as applied to claim 3 and further in view of Djupesland (6,715,485).

As to Claims 4-6 and 31, the modified Zimmerman discloses the nose piece (16) is shaped for tight sealing of the user's nostril, yet does not expressly disclose the other side of the nose piece is in the form of the truncated cone. Djupesland teaches a nose piece (30) in the shape of a truncated cone (Figure 3) for optimizing the flow pattern and particle distribution during medicament therapy. (Column 10, Lines 15-22). In light of the relationship between the nose piece and the shape, it would have been an obvious to one having ordinary skill in the art at the time the invention was made to select the appropriate shape of the nose piece with respect to the flow pattern and particle distribution needs, since it has been held that where the general conditions of a claim are disclosed, discovering the optimum workable ranges only involves routine skill in the art. In re Aller, 105 USPQ 233. Therefore, it would have been obvious to one having ordinary skill in the art to modify the nose piece shape of the modified Zimmerman, a known result effective variable, as taught by Djupesland in order to provide a nose piece

capable of providing the desired flow pattern and particle distribution during medicament therapy.

9. Claims 10, 13, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zimmerman (4,273,124) in view of Terada et al. (5,054,477), as applied to claim 1 and further in view of Rimkus (5,890,491).

As to Claim 10, the modified Zimmerman discloses the flow resistance device (34), yet does not expressly disclose the flow resistance device has a filter. Rimkus teaches the use of a filter (14) within a nose piece for the purpose of purifying and warming air (Column 1, Lines 9-10). Therefore, it would have been obvious to one having ordinary skill in the art to modify the flow resistance device of the modified Zimmerman to include a filter, as taught by Rimkus to provide purification of air.

As to Claim 13, Rimkus teaches the housing of the filter (12) is a stopper and directs air thought the air passageways (24) where a hollow space is filled by a filtering compound (14). (Column 3, Lines 40-54)

As to Claim 15, Zimmerman discloses the flow resistance device (34) has a first large diameter at (the top of 34) and a second smaller diameter at the end of the flow resistance device (34) at passageway (36).

10. Claims 14 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zimmerman (4,273,124) in view of Terada et al. (5,054,477), and Rimkus (5,890,491), as applied to claim 13 and further in view of Djupesland (6,715,485).

As to Claims 14 and 32, the modified Zimmerman discloses the flow resistance device (34), yet does not expressly disclose the flow resistance device (34) is in the form of the truncated cone. Djupesland teaches the flow resistance device (40) in the shape of a truncated cone (Figure 3) for optimizing the flow pattern and particle distribution during medicament therapy. (Column 10, Lines 15-22 and Column 11, Lines 7-29). In light of the relationship between the nose piece and the shape, it would have been an obvious to one having ordinary skill in the art at the time the invention was made to select the appropriate shape of the nose piece with respect to the flow pattern and particle distribution needs, since it has been held that where the general conditions of a claim are disclosed, discovering the optimum workable ranges only involves routine skill in the art. In re Aller, 105 USPQ 233. Therefore, it would have been obvious to one having ordinary skill in the art to modify the nose piece shape of the modified Zimmerman, a known result effective variable, as taught by Djupesland in order to provide a nose piece capable of providing the desired flow pattern and particle distribution during medicament therapy.

11. Claims 17-19, 21, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zimmerman (4,273,124) in view of Terada et al. (5,054,477) as applied to claim 16 and further in view of Sladek (4,951,661).

As to Claims 17, 18, and 21, the modified Zimmerman discloses a nebulizer (the combination of 10 and 20); yet does not expressly disclose the shared compressed air connections between the nebulizer and the air inlet flue. Sladek teaches a nebulizer

(25) having a shared compressed air connection (38, Figure 6, and Column 4, Lines 3-18) for the purpose of providing effectuate convenient attachment of the nebulizer. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the air connection between the nebulizer and the air inlet flue of the modified Zimmerman to be shared as taught by Sladek for the purpose of providing convenient attachment of the nebulizer.

As to Claims 19 and 33, the modified Zimmerman discloses the pressure fluctuations correspond to the power supply frequency of the compressed air source. Yet does not expressly disclose the operating frequency range. In light of the relationship between the pressure fluctuations and the power supply frequency, it would have been an obvious to one having ordinary skill in the art at the time the invention was made to select the appropriate pressure fluctuations with respect to the power supply frequency, since it has been held that where the general conditions of a claim are disclosed, discovering the optimum workable ranges only involves routine skill in the art. In re Aller, 105 USPQ 233. Therefore, it would have been obvious to one having ordinary skill in the art to modify the pressure fluctuations of the modified Zimmerman, a known result effective variable, in order to provide a pressure fluctuation range capable of providing the desired flow pattern during medicament therapy.

12. Claims 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zimmerman (4,273,124) in view of Terada et al. (5,054,477) as applied to claim 1 and further in view of Salter et al. (5,584,285).

As to Claims 22-24, the modified Zimmerman discloses a nebulizer (the combination of 10 and 20); yet does not expressly sensor to monitor the flow. Salter teaches a nebulizer (112) having an outlet (196) for receiving a pressure transducer monitor (231) for the purpose of monitoring the pressures generated (Column 9, Lines 50-65). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the nebulizer of the modified Zimmerman to include a sensor as taught by Salter for the purpose of monitoring the pressures generated by the nebulizer.

13. Claims 25-27 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zimmerman (4,273,124) in view of Terada et al. (5,054,477) as applied to claim 1 and further in view of Boiarski et al. (4,268,460).

As to Claim 25, the modified Zimmerman discloses a nebulizer (the combination of 10 and 20); yet does not expressly the liquid composition. Boiarski teaches a nebulizer (Figure 9) capable of aerosolizing mucolytics, antibiotics, and other liquid compositions (Column 1, Lines 24-32) for the purpose of generating medicament carrying aerosols to treat a patient. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the liquid composition of the nebulizer of the modified Zimmerman to include a aerosolizing liquid composition as taught by Boiarski for the purpose of providing aerosol therapy to the patient.

As to Claims 26 and 27, Boiarski teaches the diameter size of the nebulizer is less than 1 microns in order to be deposited in the alveoli of the lungs. (Column 9, Lines 2-6 and 33-36).

As to Claim 34, Boiarski teaches the diameter size of the nebulizer between 2 and 5 microns in order to be deposited in the lungs. (Column 1, Lines 39-56 and Column 9, Lines 2-6 and 33-36).

Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1, 2, 4, 12-14, 19, 20, 25, 27, 31, 32, and 34 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5, 6, 9-13, and 27-29 of copending Application No. 11/650,817. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claim 1 is merely broader than copending claim 1. It is clear that all of the elements of claim 1 are found in claim 1 of the copending application. The difference lies in the fact that the copending application includes many more elements and is thus much more specific. Thus, the invention of the copending application of claim 1 is in effect a "species" of the "generic" invention of instant claim 1. It has been held that the generic invention is "anticipated" by the "species". See In re Goodman, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claim 1 is anticipated by claim 1 of the copending application it is not patentably distinct from the copending claim 1. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

With respect to all the claims, both the instant invention and the copending application recite a therapeutic aerosolizing device having a nebulizer, nosepiece and flow resistance device.

The limitations of claim 13 are recited in copending claim 5. The limitations of claims 4 and 31 are recited in copending claim 6. The limitations of claims 14 and 32 are recited in copending claim 9. The limitations of claim 12 are recited in copending claim 10. The limitations of claim 19 are recited in copending claim 11. The limitations of claim 20 are recited in copending claim 12. The limitations of claim 2 are recited in copending claim 13. The limitations of claim 25 are recited in copending claim 27. The limitations of claim 34 are recited in copending claim 28. The limitations of claim 27 are recited in copending claim 29.

Response to Arguments

16. Applicant's arguments with respect to claims 1-34 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Pena (4,029,095), Davis (5,928,190), and Kronenberg (2,078,180) discloses additional devices for providing fluid into a nostril of patient while providing an additional insert for another nostril

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette F. Dixon whose telephone number is (571) 272-3392. The examiner can normally be reached on Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Annette F Dixon
Examiner
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